

What is claimed is:

1. A system for analyzing the use of medical devices comprising:
- a) geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature;
 - b) mesh generator that receives the said geometric model of said anatomical feature and the geometric model of a medical device, and generates a finite element model or mesh incorporating both said anatomical feature and said medical device; and
 - c) stress/strain/deformation analyzer that receives said mesh incorporating both said anatomical feature and said medical device, materials properties of said anatomical feature and said medical device, and load on said anatomical feature and/or said medical device, and simulates stresses, strains, and deformations of said medical device.
2. A system as defined in claim 1 where said geometric model of said anatomical feature is an idealized geometric model.
3. A system as defined in claim 1 where said three-dimensional volumetric data are acquired via CT scan.
4. A system as defined in claim 1 where said three-dimensional volumetric data are acquired via MRI.
5. A system as defined in claim 1 where said geometric model of a said medical device is for an endovascular prosthesis.
6. A system as defined in claim 5 where said endovascular prosthesis is a transluminally placed endovascular graft.

7. A system as defined in claim 5 where said endovascular prosthesis is a cardiovascular stent device.
8. A system as defined in claim 1 where said geometry generator is MIMICS.
9. A system as defined in claim 1 where said mesh generator is TRUEGRID.
- 5 10. A system as defined in claim 1 where said stress/strain/deformation analyzer is DYNA3D.
11. A system as defined in claim 1 where said stress/strain/deformation analyzer is NIKE3D.
12. A system as defined in claim 10 where said DYNA3D is modified to accommodate a strain energy density of the form:

$$\begin{aligned}
 W = & a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\
 & a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\
 & \frac{1}{2}K(I_3-1)^2
 \end{aligned}$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1 , I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green

strain tensor, respectively.

13. A system as defined in claim 11 where said NIKE3D is modified to accommodate a strain energy density of the form:

$$\begin{aligned} W = & a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ & a_{30}(I_1-3)^3 + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ 5 \quad & \frac{1}{2}K(I_3-1)^2 \end{aligned}$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1, I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green

strain tensor, respectively.

14. A system as defined in claim 1 further comprising visualization tool that receives said stresses and strains on said medical device and anatomical feature and displays said stresses and strains on said medical device via visual representation.

15. A system as defined in claim 14 where said visualization tool is GRIZ.

16. A system for analyzing the use of a medical device comprising:

a) geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of a particular individual and generates a geometric model of said anatomical feature;

b) mesh generator that receives the said geometric model of said anatomical feature and the geometric model of a medical device, and generates a finite element model or mesh incorporating both said anatomical feature and said medical device; and

c) stress/strain/deformation analyzer that receives said mesh incorporating both said anatomical feature and said medical device, materials properties of said anatomical feature and said medical device, and load on said anatomical feature and/or said medical device, and simulates stresses, strains, and deformation of said medical device.

17. A system as defined in claim 16 where said geometric model of said anatomical feature is an idealized geometric model.

18. A system as defined in claim 16 where said three-dimensional volumetric data are acquired via CT scan.

19. A system as defined in claim 16 where said three-dimensional volumetric data are acquired via MRI.

20. A system as defined in claim 16 where said geometric model of a said medical device is for an endovascular prosthesis.

21. A system as defined in claim 20 where said endovascular prosthesis is a transluminally placed endovascular graft.

22. A system as defined in claim 20 where said endovascular prosthesis is a cardiovascular stent device.

23. A system as defined in claim 16 where said geometry generator is MIMICS.

24. A system as defined in claim 16 where said mesh generator is TRUEGRID.

25. A system as defined in claim 16 where said stress/strain/deformation analyzer is DYNA3D.

26. A system as defined in claim 16 where said stress/strain/deformation analyzer is NIKE3D.

27. A system as defined in claim 25 where said DYNA3D is modified to accommodate a strain energy density of the form:

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$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 +$$
$$a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 +$$
$$\frac{1}{2}K(I_3-1)^2$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

10 where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1, I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green

15 strain tensor, respectively.

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28. A system as defined in claim 26 where said NIKE3D is modified to accommodate a strain energy density of the form:

$$\begin{aligned} W = & a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ & a_{30}(I_1-3)^3 + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ & \frac{1}{2}K(I_3-1)^2 \end{aligned}$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1 , I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green

strain tensor, respectively.

29. A system as defined in claim 16 further comprising visualization tool that receives said stresses and strains on said medical device and anatomical feature and displays said stresses and strains on said medical device via visual representation.

30. A system as defined in claim 29 where said visualization tool is GRIZ.

31. A system for analyzing the use of medical device comprising:

a) mesh generator that receives a geometric model of in vitro feature and a geometric

model of a medical device, and generates a finite element model or mesh incorporating both said in vitro feature and said medical device; and

b) stress/strain/deformation analyzer that receives said mesh incorporating both said anatomical feature and said medical device, materials properties of said anatomical

feature and said medical device, and load on said anatomical feature and/or said medical device, and simulates stresses, strains, and deformations on said medical device.

32. A system as defined in claim 31 where said in vitro feature is a geometric model of an idealized anatomical feature.

5 33. A system as defined in claim 31 where said geometric model of said medical device is for an endovascular prosthesis.

34. A system as defined in claim 33 where said endovascular prosthesis is a transluminally placed endovascular graft.

10 35. A system as defined in claim 33 where said endovascular prosthesis is a cardiovascular stent device.

36. A system as defined in claim 31 where said mesh generator is TRUEGRID.

37. A system as defined in claim 31 where said stress/strain/deformation analyzer is DYNA3D.

15 38. A system as defined in claim 31 where said stress/strain/deformation analyzer is NIKE3D.

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39. A system as defined in claim 37 where said DYNA3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + a_{30}(I_1-3)^3 + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \frac{1}{2}K(I_3-1)^2$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1, I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green

strain tensor, respectively.

40. A system as defined in claim 38 where said NIKE3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + a_{30}(I_1-3)^3 + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \frac{1}{2}K(I_3-1)^2$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1 , I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

41. A system as defined in claim 31 further comprising visualization tool that receives said stresses and strains on said medical device and anatomical feature and displays said stresses and strains on said medical device via visual representation.

42. A system as defined in claim 41 where said visualization tool is GRIZ.

43. A system for analyzing the use a of medical device comprising:

a) mesh generator that receives a geometric model of a medical device, and generates a finite element model or mesh of said medical device; and

b) stress/strain/deformation nonlinear analyzer that receives said mesh, materials properties of said medical device, and load on said medical device, and simulates stresses, strains, and deformations on said medical device.

44. A system as defined in claim 43 where said geometric model of said medical device is for an endovascular prosthesis.

45. A system as defined in claim 44 where said endovascular prosthesis is a transluminally placed endovascular graft.

46. A system as defined in claim 44 where said endovascular prosthesis is a cardiovascular stent device.

47. A system as defined in claim 43 where said mesh generator is TRUEGRID.

48. A system as defined in claim 43 where said stress/strain/deformation analyzer is DYNA3D.

49. A system as defined in claim 43 where said stress/strain/deformation analyzer is NIKE3D.

50. A system as defined in claim 48 where said DYNA3D is modified to accommodate a strain energy density of the form:

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$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 +$$
$$a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 +$$
$$\frac{1}{2}K(I_3-1)^2$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1 , I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green

15 strain tensor, respectively.

51. A system as defined in claim 49 where said NIKE3D is modified to accommodate a strain energy density of the form:

W

$$= a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 +$$
$$a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 +$$
$$\frac{1}{2}K(I_3-1)^2$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1 , I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green

5 strain tensor, respectively.

52. A system as defined in claim 43 further comprising visualization tool that receives said stresses and strains on said medical device and anatomical feature and displays said stresses and strains on said medical device via visual representation.

53. A system as defined in claim 52 where said visualization tool is GRIZ.

10 54. A computer method for analyzing a medical device comprising:

a) acquiring three-dimensional volumetric data of at least one anatomical feature;

b) generating a geometric model of said three-dimensional volumetric data;

c) receiving data representing a geometric model of a candidate medical device design;

d) receiving said geometric model of said three-dimensional volumetric data;

15 e) generating a mesh incorporating both said geometric model of said anatomical feature and said geometric model of said candidate medical device design;

f) receiving material properties of said mesh;

g) receiving load data of said mesh; and

20 h) simulating stresses, strains, and deformation imposed on said candidate medical device design by said load data.

55. A method as defined in claim 54 further comprising the step of simulating stresses, strains, and deformations to a point of failure of said candidate medical device design.

56. A method as defined in claim 54 where said three-dimensional volumetric data are acquired via CT scan.

57. A method as defined in claim 54 where said three-dimensional volumetric data are acquired via MRI.

5 58. A method as defined in claim 54 where said geometric model of a medical device is for an endovascular prosthesis.

59. A method as defined in claim 58 where said endovascular prosthesis is a transluminally placed endovascular graft.

60. A method as defined in claim 59 where said endovascular prosthesis is a cardiovascular stent device.

61. A method as defined in claim 54 where said geometric model for three-dimensional volumetric data is generated by a MIMICS software application.

62. A method as defined in claim 54 where said mesh is generated by TRUEGRID.

63. A method as defined in claim 54 where said stresses, strains, and deformations are simulated by a DYNA3D software application.

64. A method as defined in claim 54 where said stresses, strains, and deformations are simulated by a NIKE3D software application.

65. A method as defined in claim 63 where said DYNA3D is modified to accommodate a strain energy density of the form:

$$\begin{aligned} W = & a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ & a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ & \frac{1}{2}K(I_3-1)^2 \end{aligned}$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1, I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

66. A method as defined in claim 64 where said NIKE3D is modified to accommodate a strain energy density of the form:

$$\begin{aligned} W = & a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ & a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ & \frac{1}{2}K(I_3-1)^2 \end{aligned}$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1, I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

67. A method as defined in claim 54 where said stress/strain/deformation analysis is done using a non-linear finite element analysis tool.

68. A method as defined in claim 54 further comprising the step of receiving results of said stress, strain, and deformation analysis into a visualization tool and where said visualization tool visually presents the strains, stresses, and deformations on said medical device.

5 69. A method as defined in claim 68 where said visualization means is GRIZ.

70. A method for analyzing a medical device comprising:

a) acquiring three-dimensional volumetric data of at least one anatomical feature of a particular individual;

b) generating a geometric model of said three-dimensional volumetric data;

10 c) receiving a geometric model of a candidate medical device;

d) receiving said geometric model of said three-dimensional volumetric data;

e) generating a mesh incorporating both said geometric model of said anatomical feature and geometric model of said candidate medical device;

f) receiving material properties of said mesh;

15 g) receiving load of said mesh; and

h) simulating dynamic or quasi-static stresses, strains, and deformations imposed on medical device.

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71. A method as defined in claim 70 further comprising the step of simulating stresses, strains, and deformations to point of failure of said medical device.

20 72. A method as defined in claim 70 where said three-dimensional volumetric data are acquired via CT scan.

73. A method as defined in claim 70 where said three-dimensional volumetric data are acquired via MRI.

74. A method as defined in claim 70 where said geometric model of a medical device is for an endovascular prosthesis.

75. A method as defined in claim 74 where said endovascular prosthesis is a transluminally placed endovascular graft.

76. A method as defined in claim 74 where said endovascular prosthesis is a cariovascula stent device.

77. A method as defined in claim 70 where said generating geometric means for three-dimensional volumetric data is MIMICS.

78. A method as defined in claim 70 where said mesh generating means is TRUEGRID.

79. A method as defined in claim 70 where said stress/strain/deformation simulating means is DYNA3D.

80. A method as defined in claim 70 where said stress/strain/deformation simulating means is NIKE3D.

81. A method as defined in claim 79 where said DYNA3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + a_{30}(I_1-3)^3 + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \frac{1}{2}K(I_3-1)^2$$

$$\text{with } K = 2(a_{10} + a_{01}) / (1 - 2\nu)$$

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1, I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

82. A method as defined in claim 80 where said NIKE3D is modified to accommodate a strain energy density of the form:

$$\begin{aligned} W = & a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ & a_{30}(I_1-3)^3 + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ & \frac{1}{2}K(I_3-1)^2 \end{aligned}$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1, I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

83. A method as defined in claim 70 where said stress/strain/deformation analysis is done using a non-linear finite element analysis tool.

84. A method as defined in claim 70 further comprising the step of receiving results of said stress and strain analysis into a visualization tool and where said visualization tool visually presents the strains and stresses on said medical device.

85. A method as defined in claim 84 where said visualization means is GRIZ.

86. A computer method for analyzing a medical device comprising:
a) receiving data representing an in vitro model and a geometric model of a candidate medical device design;
e) generating a mesh incorporating both said geometric model of said in vitro model and
5 geometric model of said candidate medical device design;
f) receiving material properties of said mesh;
g) receiving load data of said mesh; and
h) simulating stresses, strains, and deformations imposed on said medical device by said load data.

10 87. A method as defined in claim 86 further comprising the step of simulating stresses and strains to point of failure of said medical device.

88. A method as defined in claim 86 where said geometric model of a medical device is for an endovascular prosthesis.

15 89. A method as defined in claim 86 where said endovascular prosthesis is a transluminally placed endovascular graft.

90. A method as defined in claim 88 where said endovascular prosthesis is a cardiovascular stent device.

91. A method as defined in claim 86 where said mesh generating means is TRUEGRID.

20 92. A method as defined in claim 86 where said stress/strain/deformation simulating means is DYNA3D.

93. A method as defined in claim 86 where said stress/strain/deformation simulating means is NIKE3D.

94. A method as defined in claim 92 where said DYNA3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + a_{30}(I_1-3)^3 + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \frac{1}{2}K(I_3-1)^2$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$,

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1 , I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

95. A method as defined in claim 93 where said NIKE3D is modified to accommodate a strain energy density of the form:

$$W = a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + a_{30}(I_1-3)^3 + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \frac{1}{2}K(I_3-1)^2$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$,

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1 , I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green

5 strain tensor, respectively.

96. A method as defined in claim 86 where said stress/strain/deformation analysis is done using a non-linear finite element analysis tool.

97. A method as defined in claim 86 further comprising the step of receiving results of said stress, strain, and deformation analysis into a visualization tool and where said
10 visualization tool visually presents the strains and stresses on said medical device.

98. A method as defined in claim 97 where said visualization means is GRIZ.

99. A method for analyzing a medical device comprising:

a) receiving a geometric model of a candidate medical device design;

15 b) generating a mesh of said candidate medical device design;

c) receiving material properties of said mesh;

d) receiving load of said mesh; and

e) simulating stresses, strains, and deformations imposed on said medical device.

100. A method as defined in claim 99 further comprising the step of simulating stresses and strains to point of failure of said medical device.
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101. A method as defined in claim 99 where said geometric model of a medical device is for an endovascular prosthesis.

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102. A method as defined in claim ~~99~~¹⁰¹ where said endovascular prosthesis is a transluminally placed endovascular graft.

103. A method as defined in claim 101 where said endovascular prosthesis is a cardiovascular stent device.

5 104. A method as defined in claim 99 where said mesh generating means is TRUEGRID.

105. A method as defined in claim 99 where said stress/strain/deformation simulating means is DYNA3D.

106. A method as defined in claim 99 where said stress/strain/deformation simulating means is NIKE3D.

10 107. A method as defined in claim 105 where said DYNA3D is modified to accommodate a strain energy density of the form:

$$\begin{aligned} W = & a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ & a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ & \frac{1}{2}K(I_3-1)^2 \end{aligned}$$

15 with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$,

where

a_{ij} are material parameters;

ν is Poisson's ratio;

20 K is the bulk modulus given as a function of Poisson's ratio; and

I_1, I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

108. A method as defined in claim 106 where said NIKE3D is modified to accommodate a strain energy density of the form:

$$\begin{aligned} W = & a_{10}(I_1-3) + a_{01}(I_2-3) + a_{20}(I_1-3)^2 + a_{11}(I_1-3)(I_2-3) + a_{02}(I_2-3)^2 + \\ & a_{30}(I_1-3) + a_{21}(I_1-3)^2(I_2-3) + a_{12}(I_1-3)(I_2-3)^2 + a_{03}(I_2-3)^3 + \\ & \frac{1}{2}K(I_3-1)^2 \end{aligned}$$

with $K = 2(a_{10} + a_{01}) / (1 - 2\nu)$,

where

a_{ij} are material parameters;

ν is Poisson's ratio;

K is the bulk modulus given as a function of Poisson's ratio; and

I_1, I_2 , and I_3 are the first, second, and third invariants of the right Cauchy-Green strain tensor, respectively.

109. A method as defined in claim 99 where said stress/strain/deformation analysis is done using a non-linear finite element analysis tool.

110. A method as defined in claim 99 further comprising the step of receiving results of said stress, strain, and deformation analysis into a visualization tool and where said visualization tool visually presents the strains and stresses on said medical device.

111. A method as defined in claim 110 where said visualization means is GRIZ.